PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:
BECK GREENER
Fulwood House
Attn. Burford, Anthony F.
12 Fulwood Place
London
WC1V 6HR
UNITED KINGDOM

RECEIVED
2 - NOV 2005

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference AFB/JAS/P10272WO	Date of mailing *(day/month/year)* 03/11/2005 **FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/GB2005/000415	International filing date *(day/month/year)* 07/02/2005
Applicant TILLOTTS PHARMA AG	

1. [x] The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

   When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

   Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Fascimile No.: (41-22) 740.14.35

   For more detailed instructions, see the notes on the accompanying sheet.

2. [ ] The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. [ ] **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

   [ ] the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

   [ ] no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

   The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until **30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

   In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

   See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the International Searching Authority European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Emmanuel Cherqui

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international pbulication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When? Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How? Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped),whether

(i) the claim is unchanged;

(ii) the claim is cancelled;

(iii) the claim is new;

(iv) the claim replaces one or more claims as filed;

(v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."

2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."

3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."

4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international appplication is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the same time of filing the amendments with the International Bureau, also file a copy of such amendments with the International Preliminary Examining Authority (see Rule 62.2(a), first sentence).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, where upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
AFB/JAS/P10272WO		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/GB2005/000415	07/02/2005	13/02/2004
Applicant		
TILLOTTS PHARMA AG		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 5 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**
   a. With regard to the **language,** the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
      [ ] The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).
   b. [ ] With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. [X] **Certain claims were found unsearchable** (See Box II).

3. [ ] **Unity of invention is lacking** (see Box III).

4. With regard to the **title,**
   [ ] the text is approved as submitted by the applicant.
   [X] the text has been established by this Authority to read as follows:

   SOFT GELATIN CAPSULE COMPRISING OMEGA-3 POLYUNSATURATED FATTY ACID

5. With regard to the **abstract,**
   [X] the text is approved as submitted by the applicant.
   [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings,**
   a. the figure of the **drawings** to be published with the abstract is Figure No. _____
      [ ] as suggested by the applicant.
      [ ] as selected by this Authority, because the applicant failed to suggest a figure.
      [ ] as selected by this Authority, because this figure better characterizes the invention.
   b. [ ] none of the figures is to be published with the abstract.

IN RNATIONAL SEARCH REPORT

Inte ..ional Application No
PCT/GB2005/000415

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K9/48 A61K31/557 A61P35/00 A61P3/06 A61P11/06
A61P25/18 A61P29/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, EMBASE, BIOSIS, FSTA, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 234 464 B1 (KRUMBHOLZ RUDOLF ET AL) 22 May 2001 (2001-05-22) cited in the application column 1, lines 24-32,45-51 column 2, lines 49-52; claim 1; example 1	1-7, 11-20, 25-28, 32-34
Y		23,24, 30,31

	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
27 October 2005	03/11/2005

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Marttin, E

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Form PCT/ISA/210 (second sheet) (January 2004)

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 03/086104 A (OCEAN NUTRITION CANADA LTD) 23 October 2003 (2003-10-23) page 4, lines 13-27 page 5, lines 14-24; claims 1-6,18,24; examples	1-7, 11-15, 17,18, 20,25, 32-34
Y		23,24, 30,31
Y	EP 0 289 204 A (EFAMOL HOLDINGS PLC) 2 November 1988 (1988-11-02) cited in the application	23,24, 30,31
A	page 2, lines 16-31 page 5, lines 42-49; examples 1-6	1-22
Y	BELLUZZI A: "Effect of an enteric-coated fish oil preparation on relapses in Crohn's disease" NEW ENGLAND JOURNAL OF MEDICINE, THE, MASSACHUSETTS MEDICAL SOCIETY, WALTHAM, MA, US, vol. 334, no. 24, 13 June 1996 (1996-06-13), pages 1557-1560, XP002111589 ISSN: 0028-4793	23,24, 30,31
A	page 1557, left-hand column, last paragraph - right-hand column, paragraph 2 page 1558, left-hand column, paragraphs 3,4 page 1559, left-hand column, paragraph 3	1-22
A	EP 0 100 052 A (SYNTEX INC) 8 February 1984 (1984-02-08) page 5, line 2 - page 6, line 12	1-22, 25-29
P,X	WO 2004/091317 A (BOEHRINGER INGELHEIM INTERNATIONAL GMBH; BOEHRINGER INGELHEIM PHARMA G) 28 October 2004 (2004-10-28) page 6, lines 4-29 page 12, lines 15-26; example 1	1,6-8, 11-13, 16-19, 25,32-34

IN RNATIONAL SEARCH REPORT

Information on patent family members

Inte .ional Application No
PCT/GB2005/000415

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 6234464 B1	22-05-2001	DE 19830375 A1	13-01-2000
		EP 0970623 A2	12-01-2000
		NO 992403 A	10-01-2000
WO 03086104 A	23-10-2003	AU 2003218573 A1	27-10-2003
		CA 2455971 A1	23-10-2003
		CN 1646029 A	27-07-2005
		EP 1492417 A1	05-01-2005
		JP 2005522313 T	28-07-2005
		US 2003193102 A1	16-10-2003
		US 2005019416 A1	27-01-2005
EP 0289204 A	02-11-1988	AU 618730 B2	09-01-1992
		AU 1536188 A	27-10-1988
		CA 1306944 C	01-09-1992
		DE 3863678 D1	22-08-1991
		DK 225588 A	28-10-1988
		ES 2040847 T3	16-07-1996
		GR 3002426 T3	30-12-1992
		HK 127793 A	26-11-1993
		IE 60568 B1	27-07-1994
		JP 1013021 A	17-01-1989
		JP 2699083 B2	19-01-1998
		KR 9613433 B1	05-10-1996
		NZ 224380 A	25-06-1991
EP 0100052 A	08-02-1984	AU 1695783 A	26-01-1984
		CA 1216793 A1	20-01-1987
		JP 59031711 A	20-02-1984
		NZ 204924 A	10-09-1986
		ZA 8305226 A	27-03-1985
WO 2004091317 A	28-10-2004	NONE	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB2005/000415

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

Although claims 30 and 31 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the composition.

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

PCT

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43*bis*.1)

	Date of mailing *(day/month/year)* see form PCT/ISA/210 (second sheet)
Applicant's or agent's file reference see form PCT/ISA/220	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB2005/000415	07.02.2005	13.02.2004

International Patent Classification (IPC) or both national classification and IPC
A61K9/48, A61K31/557, A61P35/00, A61P3/06, A61P11/06, A61P25/18, A61P29/00

Applicant
TILLOTTS PHARMA AG

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:

European Patent Office - P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk - Pays Bas
Tel. +31 70 340 - 2040 Tx: 31 651 epo nl
Fax: +31 70 340 - 3016

Authorized Officer

Marttin, E

Telephone No. +31 70 340-2862

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/GB2005/000415

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ in written format

   ☐ in computer readable form

   c. time of filing/furnishing:

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. II Priority

1. ☐ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43*bis*.1 and 64.1) is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

   see separate sheet

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 30. 31, with regard to industrial applicability

because:

☒ the said international application, or the said claims Nos. 30,31, with regard to industrial applicability relate to the following subject matter which does not require an international preliminary examination *(specify)*:

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the whole application or for said claims Nos. 30,31

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	☐	has not been furnished
	☐	does not comply with the standard
the computer readable form	☐	has not been furnished
	☐	does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/GB2005/000415

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	4,6-10,13-16,20-24,27,29-31
	No:	Claims	1-3,5,11,12,17-19,25,26,28,32-34
Inventive step (IS)	Yes:	Claims	8-10,21,22,29
	No:	Claims	1-7,11-20,23-28,30-34
Industrial applicability (IA)	Yes:	Claims	1-29,32-34
	No:	Claims	

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43*bis*.1 and 70.10)

and / or

2. Non-written disclosures (Rules 43*bis*.1 and 70.9)

see form 210

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item II.

The date of priority claimed can be allowed for the relevant parts of the present application.

Re Item III.

Claims 30 and 31 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

Re Item V.

1
Reference is made to the following documents (for relevant passages see search report):

D1: US-B1-6 234 464 (KRUMBHOLZ RUDOLF ET AL) 22 May 2001 (2001-05-22)
D2: WO 03/086104 A (OCEAN NUTRITION CANADA LTD) 23 October 2003 (2003-10-23)
D3: EP-A-0 289 204 (EFAMOL HOLDINGS PLC) 2 November 1988 (1988-11-02)
D4: BELLUZZI A: "Effect of an enteric-coated fish oil preparation on relapses in Crohn's disease" NEW ENGLAND JOURNAL OF MEDICINE, THE, MASSACHUSETTS MEDICAL SOCIETY, WALTHAM, MA, US, vol. 334, no. 24, 13 June 1996 (1996-06-13), pages 1557-1560, XP002111589 ISSN: 0028-4793

2
Document D1 discloses eicosapentaenoic acid ethyl ester (EPA) which has been microencapsulated in gelatin A to increase the stability. The microcapsules are considered to be soft capsules .

2.1
INDEPENDENT CLAIM 1

As can be seen from the above, document D1 discloses in combination all the features defined in independent claim 1. Hence the subject-matter of this claim is not new (Article 33(2) PCT).

2.2
INDEPENDENT CLAIM 25

As can be seen from the above, document D1 discloses in combination all the features defined in independent claim 25. Hence the subject-matter of this claim is not new (Article 33(2) PCT).

2.3
INDEPENDENT CLAIM 26

As can be seen from the above, document D1 discloses in combination all the features defined in independent claim 26. Hence the subject-matter of this claim is not new (Article 33(2) PCT).

2.4
INDEPENDENT CLAIM 28

As can be seen from the above, document D1 discloses in combination all the features defined in independent claim 28. Hence the subject-matter of this claim is not new (Article 33(2) PCT).

2.5
INDEPENDENT CLAIM 32

As can be seen from the above, document D1 discloses in combination all the features defined in independent claim 32. Hence the subject-matter of this claim is not new (Article 33(2) PCT).

2.6
INDEPENDENT CLAIM 33

As can be seen from the above, document D1 discloses in combination all the features defined in independent claim 33. Hence the subject-matter of this claim is not new (Article 33(2) PCT).

2.7
INDEPENDENT CLAIM 34

As can be seen from the above, document D1 discloses in combination all the features defined in independent claim 34. Hence the subject-matter of this claim is not new (Article 33(2) PCT).

3
Document D2 discloses a fish oil concentrate containing 30% EPA and 20% docosahexaenoic acid ethyl ester, which has been microencapsulated in gelatin A. The shell of the microcapsules has a foam-like structure and is thus considered to be soft capsule.

3.1
INDEPENDENT CLAIM 1

As can be seen from the above, document D2 discloses in combination all the features defined in independent claim 1. Hence the subject-matter of this claim is not new (Article 33(2) PCT).

3.2
INDEPENDENT CLAIM 25

As can be seen from the above, document D2 discloses in combination all the features defined in independent claim 25. Hence the subject-matter of this claim is not new (Article 33(2) PCT).

3.3
INDEPENDENT CLAIM 32

As can be seen from the above, document D2 discloses in combination all the features defined in independent claim 32. Hence the subject-matter of this claim is not new (Article 33(2) PCT).

3.4
INDEPENDENT CLAIM 33

As can be seen from the above, document D2 discloses in combination all the features defined in independent claim 33. Hence the subject-matter of this claim is not new (Article 33(2) PCT).

3.5
INDEPENDENT CLAIM 34

As can be seen from the above, document D2 discloses in combination all the features defined in independent claim 34. Hence the subject-matter of this claim is not new (Article 33(2) PCT).

4

Document D3 discloses the use of soft gelatin capsules comprising lithium salts of omega-3 polyunsaturated fatty acids for the treatment of inflammatory conditions, hyperlipidaemia, hypertriglyceridaemia, asthma, and neoplastic disease.

4.1

INDEPENDENT CLAIM 23

Document D3, which can be considered to represent the most relevant state of the art, discloses a method from which the subject-matter of independent claim 23 differs in that the capsule comprises type A gelatin.

The problem to be solved by the present invention may therefore be regarded as the provision of an alternative type of gelatin for the soft gelatin capsules comprising at least one omega-3 polyunsaturated fatty acid for the treatment of chronic inflammatory conditions.

In view of D1 or D2 the solution proposed in claim 23 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT) for the following reasons: soft gelatin microcapsules comprising type A gelatin and an omega-3 polyunsaturated fatty acid are known from D1 or D2. It would be obvious to the person skilled in the art to replace the gelatin in document D3 with the gelatin type A of document D1 or D2, without exercise of any inventive skills in order to find an alternative gelatin for the capsule. The proposed solution in independent claim 23 thus cannot be considered inventive (Article 33(3) PCT).

4.2

INDEPENDENT CLAIM 30

The same applies mutatis mutandis to the subject-matter of claim 30. The proposed solution in independent claim 30 thus cannot be considered inventive (Article 33(3) PCT).

5

Document D4 discloses enteric coated (Eudragit NE30D) Purepa® soft gelatin fish-oil capsules for treatment of Crohn's disease, a chronic inflammatory disease.

5.1

INDEPENDENT CLAIM 23

Document D4, which can also be considered to represent the most relevant state of the art, discloses a method from which the subject-matter of independent claim 23 differs in that the capsule comprises type A gelatin.

The problem to be solved by the present invention may therefore be regarded as the provision of an alternative type of gelatin for the soft gelatin capsules comprising at least one omega-3 polyunsaturated fatty acid for the treatment of chronic inflammatory conditions.

In view of D1 or D2 the solution proposed in claim 23 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT) for the following reasons: soft gelatin microcapsules comprising type A gelatin and an omega-3 polyunsaturated fatty acid are known from D1 or D2. It would be obvious to the person skilled in the art to replace the gelatin in document D4 with the gelatin type A of document D1 or D2, without exercise of any inventive skills in order to find an alternative gelatin for the capsule. The proposed solution in independent claim 23 thus cannot be considered inventive (Article 33(3) PCT).

5.2

INDEPENDENT CLAIM 30

The same applies mutatis mutandis to the subject-matter of claim 30. The proposed solution in independent claim 30 thus cannot be considered inventive (Article 33(3) PCT).

6

DEPENDENT CLAIMS 2-7, 11-20, 24, 27, 31

Dependent claims 2-7, 11-20, 24, 27, 31 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT).

7
DEPENDENT CLAIMS 8-10, 21, 22, 29

The combination of the features of dependent claims 8-10, 21, 22, 29 are neither known from, nor rendered obvious by, the available prior art. The reasons are as follows: documents D1 and D2 disclose microcapsules, there is no hint nor suggestion in these documents to use gelatine type A for larger capsules which can contain at least 500 mg of formulation (claims 8-10). Documents D1 and D2 do also not suggest to use neutral polyacrylate polymers as an enteric coating of the capsules (claims 21 and 22). Document D1 is concerned with the provision of more stable formulations of eicosapentaenoic acid, but gelatin type A or type B can be used, so the skilled person would not assume based on D1 that gelatin type A capsules would result in a greater shelf life than gelatin type B capsules (claim 29).

8
For the assessment of the present claims 30 and 31 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Re Item VI.

Certain published documents

Application No Patent No	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date *(valid claim)* *(day/month/year)*
WO 2004/091317A	28-10-2004	14-04-2004	17-04-2003

Document WO 2004/091317A (E) discloses a soft gelatin capsule comprising 150 mg DHA (20% weight of the formulation). The capsule material can be porcine gelatin type A. Document E appears to be relevant for claims 1, 6-8, 11-13, 16, 17-20, 25, 32-34.

This document will be relevant for novelty in the regional phase.

Re Item VII.

Claims 1, 2, 27 and 35 contravene the requirements of Rule 6.2(a) PCT, since they rely, in respect of the technical features of the invention, on references to the description or drawings, namely "as hereinbefore defined" and "substantially as described, with reference to the drawings, herein".

Re Item VIII.

1
The application does not meet the requirements of Article 6 PCT, because claims 17-20, 23, 26, 28, and 30 are not clear.

1.2
Although claims 23, 26, 28 and 30 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought or in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.

1.3

Claims 17 and 18 do not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claims attempt to define the subject-matter in terms of the result to be achieved, i.e. "wherein the capsule delays release of the formulation until after passage through the stomach" (claim 17) or "wherein the capsule delays release of the formulation until after passage beyond the pancreatic duct in the duodenum" (claim 18), which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result.

1.4

Claims 19 and 20 do not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The following functional statements do not enable the skilled person to determine which technical features are necessary to perform the stated function: "enteric material".